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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,637	11/14/2003	Robert J. Dunki-Jacobs	END-5240	2410

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EXAMINER	
LAURITZEN, AMANDA L	
ART UNIT	PAPER NUMBER
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,637	DUNKI-JACOBS ET AL.	
	Examiner	Art Unit	
	Amanda L. Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/12/2006 have been fully considered but they are not persuasive.

1. Applicant points out a failure to cite any portion of Kovacs et al. that teaches an act of "marking target cells" in a patient as recited in claim 12. Examiner calls attention to col. 1, line 65 in which a dye is used to mark tissue and col. 2, lines 36-39 in which Fourier transformed data is used in spectroscopy to detect "any physical property related to an organism" (col. 1, lines 58-59), which includes the mere act of determining whether a particular tissue is present.

2. Applicant asserts that Kovacs et al., Iddan et al. and Okada et al. fail to teach a detector, a pulse shaping device, and at least one single channel analyzer as in independent claim 1. Examiner calls attention to Iddan et al. at col. 3, lines 32-33 in which a detector is disclosed within the capsule. Okada et al. disclose a radiation detector, pulse-shaping circuits and a single-channel analyzer at col. 10, lines 13-29, and establishes that this technology is known within the art of performing photon counting operations for an organism injected (i.e. marked) with a radioactive substance (col. 1, lines 19-22). The components of Okada et al. could be encapsulated and coated for ease of transfer through the GI tract (as taught by Iddan et al. at col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). It would have been obvious to modify the device of Kovacs et al. to be swallowable and coated as taught by Iddan et al. in order to enable natural progression through the GI tract, and to further modify to include the pulse-shaping circuits and single-channel analyzer of the probe of Okada et al. for the purpose of measuring the concentration of radiation in a certain area of an object or organism treated with a radioactive substance (col. 1, lines 19-22; 26-27).

3. Regarding applicant's arguments directed to claim 11, the detector of Kovacs et al. is shown to determine whether a particular tissue is present as described in above section 1. The substance associated with the particular tissue that is detected can be taken either as the dye marking substance (as in Kovacs et al.) or the radioactive marking substance (as in Okada et al., the motivation for combining provided in above section 2). The "target tissue" or "particular tissue" as recited in the claims are interpreted to encompass any desired tissue of interest.

4. Regarding applicant's arguments directed to claim 28, in reciting the limitation, "providing a substance having an affinity for a particular target tissue type" and determining whether a particular target tissue is present in the patient, Examiner calls attention to col. 2, lines 7-8 of Okada et al. for "detecting the distribution of radiation" in an organism. Different tissue types naturally have varying affinity for radioactive substances and likewise, the distribution of radiation will depend on that affinity. Therefore a measure of the distribution of radiation will correspond to target tissue distribution and the presence of target tissues with a high affinity for radiation will be identifiable.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12-27 are rejected under 35 U.S.C. 102(b) as being anticipated by ***Kovacs et al*** (US 5,833,603).

Kovacs et al anticipate disclose all claimed features in claims 12-27.

Claim 12: Kovacs et al disclose a system and method for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). Kovacs et al disclose that the detected signals and analyzed mathematically and determined whether a particular tissue is present in the patient such as temporary implants, prosthesis, patient's organs and tissues (col. 3, lines 24-32).

Claims 13-18: Kovacs et al further disclose the method above where steps of verifying at least one component and concentration (amount of chemical or biochemical substance) of the physical properties of the tissue, cell, and biochemical components of region of interest. Although, Kovacs et al do not explicitly state that the detection substance is a monoclonal body, peptide, nanoparticle, mRNA and DNS corresponding to a generic monoclonal antibody, and liposome, these are inherent properties of biochemical composition of the tissues and cells (col. 6, lines 26-36).

Claims 19-23: Kovacs et al disclose that the biosensor detects energy spectra via optical or photosensor, which is used along with dye to acquire optical radiation. Although Kovacs et al do not explicitly state use or radioisotopes, the dye solution with radiation optical acquisition is inherent that the dye solution must be radioactive or radioisotopes (col. 1, lines 56-65; col. 4, lines 34-44; col. 5, lines 5-26).

Claims 24-27: Kovacs et al further discloses the method above where the sensor is a spectrophotometer acquiring multiple images of data from a region of interest with predetermine

spectrum , wavelengths, and position to detect optical spectrum, i.e. spatial response pattern (col. 1,line 66 – col. 2, line 11).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Kovacs et al*** in view of ***Iddan et al*** (US 5,604,531) and ***Okada et al*** (US 5,424,546).

Kovacs et al substantially anticipate all claimed features in claims 1-11 and 28-31. Kovac et al disclose a system for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). In addition, Kovacs et al disclose that the capsule includes multiple detectors, a radiation detector, magnetic detector, and single analyzer for each detector (col. 4, lines 35-44). Although Kovacs et al disclose implantation of the sensor device, Kovacs et al do not disclose that the capsule is a swallowable or that the capsule material is coated to allow the capsule to goes through the gastro-intestinal (GI) tract. However, Kovacs et al's deficiency is well known in the art where Iddan et al teaches a similar capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract (col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). In addition, neither Kovacs et al nor Iddan et al specifically disclose that detector pulse shaping device is in direct communication

with a single channel analyzer configured to analyze the voltage output. This particular feature is well known in the art as evident by Okada et al. Okada et al teach that an endoscopic or catheter with a detector includes single channel analyzer that counts the detected photons, i.e. voltage output from the pulse shaping device (col. 10, lines 13-29). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Kovacs et al's teachings as described above with Iddan et al's device designed to be swallow through the GI tract and Okada et al's single channel analyzer to achieve the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.L.L.
12/18/2006

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER